

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,935	05/03/2001	David F. Woodward	D2914	6555
33197	7590	11/13/2003	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP			FUBARA, BLESSING M	
4 VENTURE, SUITE 300			ART UNIT	
IRVINE, CA 92618			PAPER NUMBER	
			1615	

DATE MAILED: 11/13/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,935

Applicant(s)

WOODWARD ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-41, 43-50, 53-66, 68 and 70-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-41, 43-50, 53-66, 68 and 70-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1615

DETAILED ACTION

Examiner acknowledges receipt of change of address filed 12/23/02; supplemental IDS filed 07/15/03; request for extension of time and non-compliant and non-entered amendment filed 05/05/03; terminal disclaimer filed 05/05/03 and supplemental amendment filed 08/25/03. Claims 36-41, 43-50, 53-66, 68 and 70-77 are pending.

Applicants' specification on page 13 discloses linolenic acid, arachidonic acid and oleic acid as unsaturated fatty acids (line 11) and prostanoid as any group of complex fatty acids derived from arachidonic acid and prostaglandin; protanoic acid and thromboxanes are examples (lines 25-28).

Oath/Declaration

The objection to the declaration is withdrawn because applicants submitted supplemental declaration.

Claim Rejections - 35 USC § 112

The rejection of claims 43 and 63 under 35 USC 112, first and second paragraph is withdrawn in light of the amendments filed 08/25/03. The rejection of claims 42 and 64 under 35 USC 112, second paragraph is withdrawn in light of the amendment filed 08/25/03.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' arguments with respect to claims 36-41, 43, 44, 47-50, 53, 54, 57 and 69 as the rejection relates to Hanssler et al. (DE 3309765), Kelly et al. (US 5,118,493) and Dean et al.

Art Unit: 1615

(US 6,242,442) have been considered but the rejection is withdrawn since linoleic acid and lecithin are not prostanoids and since Kelly and Dean do not teach prostanoids.

Claims 36, 37, 41, 43, 44, 46-50, 53, 54, 57 and 59 remain rejected under 35 U.S.C. 102(b) as being anticipated by FR 2272684 (Derwent Database on West).

Applicants' argument that FR 2272684 does not teach prostanoid is not persuasive because prostanoid is any group of complex fatty acids derived from arachidonic acid as disclosed by applicants on page 13, lines 25-28). Arachidonic acid derived fatty acid meets the limitation of prostanoid.

FR 2272684 discloses a composition comprising fatty acid and antibiotic (abstract). A complex would inherently form a complex in a mixture comprising a therapeutic component and fatty acid. And the invention broadly claims a composition comprising a therapeutic component and an efficiency-enhancing component selected from the group consisting of anionic polymer and fatty acids. Specifically FR 2272684 lists oleic acid, arachidonic acid, linolenic acid and linolenic as the fatty acids. Future intended use is not critical in a composition claim. Thus the teachings of FR 2272684 meet the limitations of the claim.

2. Claims 36-41, 43, 44, 47-50, 53-58, 70-75 and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Garst (US 6,294,563).

Garst discloses a composition that comprises brimonidine and prostaglandin (column 3, line 38 and column 4, lines 49-52). Garst's composition further comprises vegetable oils, ethyl cellulose, ethyl oleate, polyvinylpyrrolidone and isopropyl myristate; emulsifying, preserving, wetting or bodying agents (column 10, lines 1-25) or water-soluble polymer carrier (column 10, lines 38-50). Garst further discloses that the composition can contain one or more brimonidine

Art Unit: 1615

derivatives and one or more prostaglandins (column 8, line 60 to column 9 line 10).

Brimonidine is quinoxaline and alpha-2-adrenergic agonist and is a 5-bromo-6 (2-imidazolin-2-ylamino) quinoxaline. Prostaglandin is a prostanoid. No amounts and/or conditions were recited in the instant claims that would allow the composition of the application to form a complex and exclude the same composition in the prior art from forming a complex. The property of a composition cannot be separated from the composition. The teaching of Garst meets the limitations of the claims.

3. Claims 60-66, 68, 72 and 73 rejected under 35 U.S.C. 102(e) as being anticipated by Gil et al. (US 6,294,553).

Gil discloses a composition that comprises brimonidine, which is a 5-bromo-6 (2-imidazolin-2-ylamino) quinoxaline and an alpha-2-agonist (abstract, column 2, lines 50 and 61, column 3, lines 12, and 37-39), oleic acid or anionic surfactant (column 4, lines 20-22), buffers (column 4, lines 28-37), physiological saline solution and vehicles such as poloxamers and cellulose polymers (column 4, lines 4-10); the composition of Gil is applicable as an ophthalmic with a physiological saline solution as the vehicle and where the pH of the ophthalmic is between 6.5 and 7.2 (column 3, lines 65-67). Oleic acid is a fatty acid. Effective amount is any amount. A pH of 7.2 is greater than 7 and lies between 7 and 9. The teaching of Gil meets the limitations of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1615

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 45 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garst (US 6,294,563) and Dean et al. (US 6,242,442).

The teaching of Garst is discussed above. Garst clearly teaches the composition of the instant claims except that Garst does not teach a composition that further contains linolenic acid. Regarding the pH of the composition, Dean teaches a composition comprising brimonidine and the pH of this composition is between 6.5 and 7.8. One having ordinary skill in the art would prepare a composition that comprises brimonidine that has a pH of between 6.5 and 7.8, which is about the physiological pH.

Specifically, Dean discloses a composition comprising brinzolamide, brimonidine tartrate, mannitol, purified water, tyloxapol, carbopol, benzalkonium chloride, sodium chloride and disodium EDTA (examples 6-9). Brinzolamide is a carbonic anhydrase inhibitor (column 1, lines 11-13 and column 3, line 31) and brimonidine tartrate is quinoxaline and alpha-2-adrenergic agonist (column 1, lines 19-26). Water is a carrier and benzalkonium chloride is an antiseptic. Dean teaches that the pH of the brinzolamide and brimonidine formulation is between 6.5 and 7.8 (column 5, lines 28-32).

Both compositions of Dean and Garst are ophthalmic compositions. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

Art Unit: 1615

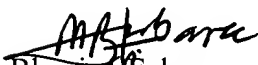
combine the two compositions to make a third composition since each composition is used for the same purpose. One having ordinary skill in the art would have been motivated to prepare a third composition with the expectation that the third composition will be suitable as an ophthalmic composition. One fatty acid can be replaced with another fatty acid with the expectation that the property or the intended use of the composition is not altered.

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.


Blessing Fubara
Patent Examiner
Tech. Center 1600